

MAY 12 1998



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Washington, D.C. 20231

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Martha A. Gammill  
Intellectual Property Services  
Pharmacia & Upjohn  
301 Henrietta St.  
Kalamazoo, MI 49001

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,902,683

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,902,683, which claims the animal drug product EXCENEL® (ceftiofur hydrochloride), and the method of use of and manufacturing of EXCENEL®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 460 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 460 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 28, 1997 (62 Fed. Reg. 9195). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (881) + 19 \\ &= 460 \text{ days}\end{aligned}$$

Since the regulatory review period began November 10, 1993, after the patent issue date (February 20, 1990), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,902,683
Granted	:	February 20, 1990
Original Expiration Date <sup>1</sup> :	:	February 20, 1997

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Applicant	:	Mahendra I. Amin et al.
Owner of Record	:	Pharmacia & Upjohn Company
Title	:	Crystalline Cephalosporin Hydrohalide Salts
Classification	:	514/206
Product Trade Name	:	EXCENEL® (ceftiofur hydrochloride)
Term Extended	:	460 days
Expiration Date of Extension	:	May 25, 2008

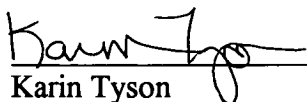
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at  
(703) 306-3159.

  
Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: EXCENEL® Sterile Suspension  
FDA Docket No.: 96E-0269